K010266

MAR 1 6 2001

510(k) Summary of Safety and Effectiveness

Triage® B-Type Natriuretic Peptide (BNP) Test

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: **(To be determined)**

A. Name and Address of Submitter

Company Name:	Biosite Diagnostics, Incorporated
Address:	11030 Roselle Street San Diego, CA 92121
Telephone:	(858) 455-4808
Fax:	(858) 535-8350
Contact Person:	Jeffrey R. Dahlen, Ph.D.
Date Summary Prepared:	1/26/00

B. Device Names

1. Trade Name

   Triage® B-Type Natriuretic Peptide (BNP) Test

2. Common / Usual Name

   BNP Test

3. Classification Name

   B-Type Natriuretic Peptide Test System

C. Predicate Devices

None

D. Device Description and Intended Use

The Triage® B-Type Natriuretic Peptide (BNP) Test is a fluorescence immunoassay that measures BNP in whole blood and plasma specimens anticoagulated with EDTA. The Triage® BNP Test is intended for use as an aid in the diagnosis of congestive heart failure (CHF).

E. Summary of Performance Data

Linearity: The assay is linear throughout the measureable range of the test.

Analytical Sensitivity: The average 95% confidence limit of the analytical sensitivity of the Triage® BNP Test is less than 5 pg/mL (95% confidence interval 0.2 - 4.8 pg/mL).

Interfering Substances: Hemoglobin (up to 10,000 mg/dl), lipids (cholesterol up to 1,000 mg/dl and triglycerides up to 1,000 mg/dl) or bilirubin (up to 20 mg/dl) added to plasma specimens containing BNP did not interfere with the measurement of BNP in a blood specimen. Additionally, there was no cross-reactivity or interference with the BNP measurement caused by any members of a panel of pharmaceutical drugs representing the concentrations that would result from either a maximal or twice the therapeutic dosage and related proteins and peptides.

Imprecision: The average total imprecision ranged from 10.1% to 16.2% using three control materials within the measurable range of the test.

Correlation Between Whole Blood and Plasma: A comparison study performed on EDTA whole blood vs. plasma shows r=0.9878, y= 0.925x + 13.439.

F. Summary of Clinical Data

The circulating BNP concentration was determined using the Triage® BNP Test from 1286 individuals without CHF and from 804 patients diagnosed with CHF. The most appropriate decision threshold is 100 pg/ml. This value translates into a general specificity of the test of 98% and a general sensitivity of the test of greater than 80%. There are no statistically significant changes in BNP concentration associated with hypertension, diabetes, renal insufficiency, and chronic obstructive pulmonary disease. A receiver operating characteristic curve of decision thresholds versus clinical sensitivity and specificity for the non-CHF and CHF groups yielded an area under the curve of 0.955 ± 0.005.

G. Conclusion

The results of performance and clinical studies demonstrate that the Triage® BNP Test is safe and effective as an aid in the diagnosis of CHF, regardless of age.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 6 2001

Jeffrey R. Dahlen, Ph.D.
Principal Scientist
Clinical & Regulatory Affairs
Biosite Diagnostics
11030 Roselle Street
San Diego, CA 92121

Re: K010266
Trade Name: Triage® B-Type Natriuretic Peptide (BNP) Test
Regulatory Class: II
Product Code: NBC
Dated: January 26, 2001
Received: January 29, 2001

Dear Dr. Dahlen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): ~~(to be determined)~~ K010266

Device Name: Triage® B-Type Natriuretic Peptide (BNP) Test

Indications For Use:

The Triage® B-Type Natriuretic Peptide (BNP) Test is used as an aid in the diagnosis of congestive heart failure (CHF).

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010266

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)